

Shimakawa, Tomoko

From: Shimakawa, Tomoko
Sent: Tuesday, February 22, 2005 11:00 AM
To: 'divulge@xtra.co.nz'
Cc: Anderson, Shellee
Subject: Your February 14, 2005 email message to Shellee Anderson

Dear Valerie & Richard James:

I would like to respond to your February 14, 2005 email message to Shellee Anderson.

On November 5, 2004, FDA met with the Solae Company at the company's request. Please see the attachment for the information regarding the meeting. The meeting with the Solae Company was not out of the ordinary because the agency can meet with petitioners when a meeting is requested by them. However, the agency does not discuss the outcome of a petition with anyone, including the petitioner, until final action is taken on the petition.

FDA has not made any final decisions regarding the Solae Company's petition. The agency considers all pertinent information in deciding how to respond to petitions.

I hope this is helpful.



Meeting with Solae
11-5-2004.w...

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2004Q-0151

ANS 1

Memorandum of Meeting

Date: November 5, 2004

Location: Room 2B047, Harvey W. Wiley Federal Building, College Park, MD

Participants:

Visitors

Jean Heggie, Marketing Leader, North America Food, Solae, LLC

Lin Yan, Ph.D., Director, Cancer Research, Solae, LLC

Gerona Berdak, Director, Public Affairs, Solae, LLC

Susan Potter, Ph.D., Global Director, Health and Nutrition, Solae, LLC

FDA, Center for Food Safety and Applied Nutrition (CFSAN)

Alan Levy, Ph.D., Consumer Studies Scientist, Division of Market Studies, OSAS

Brenda Derby, Ph.D., Statistician, Division of Market Studies, OSAS

Heather Banuelos, General Attorney, Office of General Council

Kathleen Ellwood, Ph.D., Director, Division of Nutrition Programs and Labeling, ONPLDS

Claudine Kavanaugh, Ph.D., Biologist, Division of Nutrition Programs and Labeling, ONPLDS

Tomoko Shimakawa, Sc.D., Epidemiologist, Division of Nutrition Programs and Labeling,
ONPLDS

Subject: Soy protein and cancer qualified health claim

This meeting was held at the request of the Solae Company. Ms. Jean Heggie presented consumer research findings on claim language options and their rationale for requesting changes in the wording of the model qualified health claims. Dr. Lin Yan presented results from several studies that the Solae Company submitted recently to FDA. Ms. Gerona Berdak asked some questions regarding timing of health claim decision and press release.

Tomoko Shimakawa, Sc.D.